



**CLINICAL  
DIAGNOSTICS**

## **Expert BioSpecimen Sourcing**

Validation, Verification, and  
Qualification Material







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## PANELS

SeraCare's portfolio of validation and qualification panels allows clinicians and researchers to assess overall assay performance. Whether generating validation data for a regulatory submission or performing assay verification in a clinical lab setting, our panel products offer a comprehensive solution to rigorously evaluate your infectious disease tests. With so many options, selecting which panel type to use and for what purpose can be daunting, especially when an ACCURUN Serological or Molecular control could also be considered. The Control and Panel Selection Guide (Table 1) will help select your best options for Method Validation, Compliance and Daily QC needs.

# VALIDATION, VERIFICATION, AND QUALIFICATION MATERIAL

## HIGHLY CHARACTERIZED

SeraCare provides a comprehensive and highly characterized set of data for all validation and qualification panels to support the demanding needs of IVD assay development. Our panels serve as valuable tools to support compliance with FDA and EU IVDR requirements for assay clearance. Our suite of products will allow you to confidently develop, challenge, troubleshoot, verify and validate your assay from initial proof of concept to production and beyond.

## LEADING SUPPLIER

Our Panels and Disease State Materials are so highly regarded that they are referenced in IVD manufacturers' package inserts, comparative test kit studies and peer-reviewed scientific journals, paving the way forward for assays' regulatory submission. Our Panels have also been referenced by the World Health Organization for comparative studies of HIV test kit performance.<sup>1</sup>

**TABLE 1: CONTROL AND PANEL SELECTION GUIDE**

	ACCURUN Serological Controls	ACCURUN Molecular Controls	AccuTrak Qualification Panels	AccuSpan Linearity Panels	AccuSet Performance Panels	AccuVert Seroconversion Panels
<b>METHOD VALIDATION</b>						
Evaluate antibody/antigen test sensitivity	●				●	●
Evaluate nucleic acid test sensitivity		●	●			
Evaluate test specificity					●	●
Evaluate test precision	●	●				
Evaluate test linearity			●			
<b>COMPLIANCE</b>						
Protocol training/competency			●			
Document regulatory compliance	●	●	●		●	●
<b>DAILY QC</b>						
Perform reagent lot acceptance	●	●	●			
Troubleshoot	●	●	●	●		
Perform daily run control	●	●				
Perform inter-site comparison			●	●	●	
Monitor for test interference/contamination	●	●			●	

**KEY**

- Best choice
- Can be used, other product may work better

1. WHO (2015) HIV Assays: Lab Performance and Other Operational Characteristics. Report 18. Rapid Diagnostic Tests ([https://www.who.int/diagnostics\\_laboratory/evaluations/hiv/en/](https://www.who.int/diagnostics_laboratory/evaluations/hiv/en/))

## INTEGRATE WITH ACCURUN® CONTROLS

Validating and qualifying your assay throughout its development is a necessary and time-consuming process. SeraCare's panels make that job easier. Consider also incorporating SeraCare's ACCURUN Controls to your quality control workflow so that once you've completed your assay validation, ACCURUN Controls will reassure you that your assay is running at optimal performance.

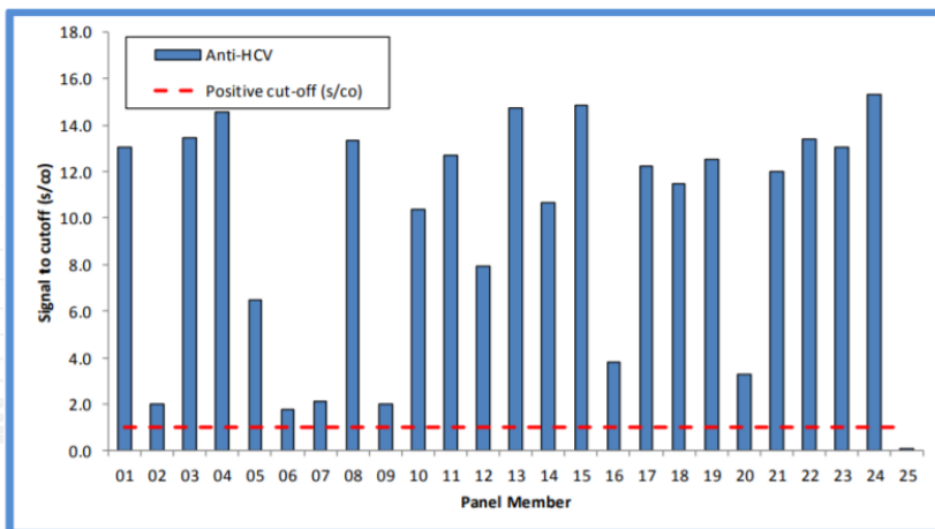
SERACARE  
DEVELOPED THE  
INDUSTRY'S FIRST  
SEROCONVERSION  
PANELS BACK IN  
THE 1980'S.

## PERFORMANCE PANELS

AccuSet™ Performance Panels consist of naturally occurring plasma samples collected from multiple donors of varied analyte concentrations, genotypes and/or demographic diversity. Panel members are characterized by disease markers across multiple test methods and platforms to provide comparative data sets for your evaluation. This allows you to benchmark your assay's performance against other industry leading manufacturers. Use our performance panels to evaluate assay specificity, sensitivity, and reproducibility throughout assay development and validation.

## QUALIFICATION PANELS

AccuTrak™ Qualification Panels are consistently manufactured from human plasma or serum positive for disease state analytes with confirmed reactivity in serological, molecular, or genotype assays. AccuTrak™ Qualification Panels are designed as a reliable, consistent, cost-effective solution for your assay's QC program. These panels are well-suited for troubleshooting and lot change evaluations. They also serve as an excellent source of affordable reference materials for personnel training on new and existing equipment.



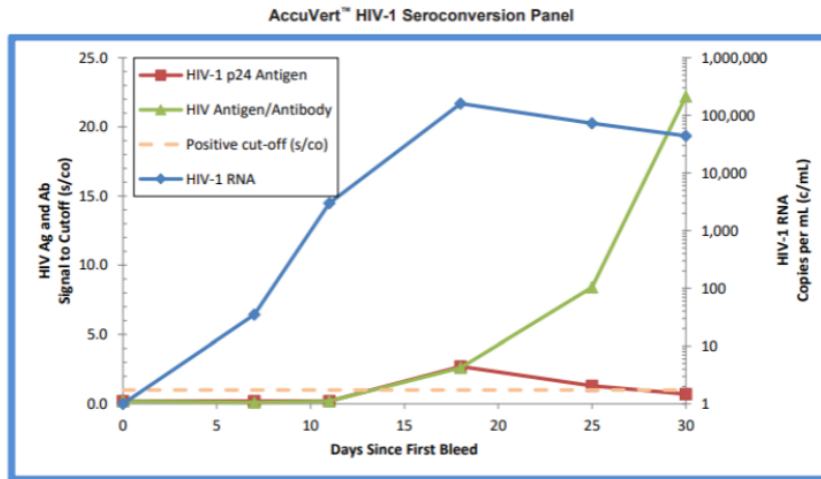
**FIGURE 1: EXAMPLE OF PERFORMANCE DATA FROM THE ACCUSET™ HCV PERFORMANCE PANEL TESTED FOR ANTI-HCV ON THE ABBOTT ARCHITECT TEST METHOD.**



**TABLE 2: AVAILABLE ANALYTES BY PANEL**

ANALYTES/TARGETS	ACCUSPAN LINEARITY PANELS	ACCUVERT SEROCONVERSION PANELS	ACCUSET PERFORMANCE PANELS	ACCUTRAK QUALIFICATION PANELS
Autoimmune			●	
Babesia			●	
Chagas		●	●	
CMV	●	●	●	●
Dengue			●	●
EBV			●	
HAV		●	●	
HBV	●	●	●	●
HCV	●	●	●	●
HIV	●	●	●	●
HPV				●
HSV			●	
HTLV			●	●
Lyme			●	
Rubella			●	
Syphilis		●	●	●
Toxoplasmosis			●	
West Nile		●		
Zika	●		●	
SARS-CoV-2		●	●	





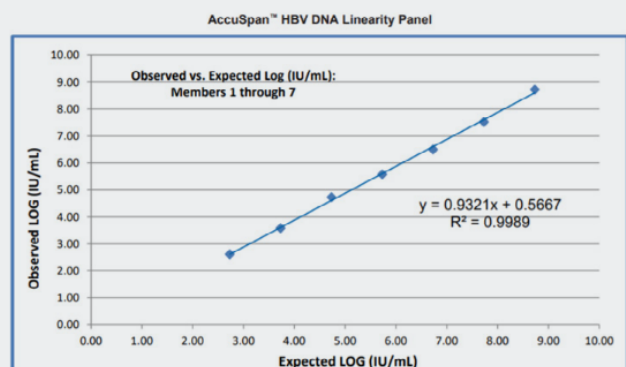
**FIGURE 2: THIS GRAPH DEMONSTRATES THE EVOLUTION OF HIV MARKERS IN EARLY INFECTION FROM OUR ACCUVERT™ HIV-1 SEROCONVERSION PANEL 0600-0272.**

## SEROCONVERSION PANELS

AccuVert™ Seroconversion Panels consist of naturally occurring plasma samples collected from a single donor during the development and progression of infection and subsequent immune response. Each seroconversion panel represents a unique donor and is characterized across multiple test methods and platforms to provide comparative data sets for each analyte. These rare panels are ideal for confirming that an assay can detect disease in patient samples at different stages of infection, and are required for regulatory submissions in some regions. Seroconversion panels are manufactured in a cGMP facility to ensure each batch provides consistent, reliable material to challenge your assay during its development.

## LINEARITY PANELS

AccuSpan™ Linearity Panels consist of serially diluted samples from high-titer recombinant, cultured or naturally occurring whole viruses that span the entire or partial analytical range of an assay for a given analyte. Panel members are calibrated against the latest WHO international standards for informational purposes and to ensure traceability. Linearity Panels can be used in assay verification procedures, operator training, troubleshooting and for bi-annual AMR lab accreditation procedures. The panels are designed to span the dynamic range of quantitative infectious disease assays and evaluate instrumentation analytical sensitivity.



**FIGURE 3: EXAMPLE RESULTS OF THE ACCUSPAN™ HBV RNA LINEARITY PANEL TESTED AGAINST THE ROCHE COBAS® AMPLIPREP/COBAS® TAQMAN® HBV VERSION 2.0 TEST METHOD.**



## DISEASE STATE MATERIALS

SeraCare's portfolio of disease state specimens and high-titer viral isolates supports IVD manufacturers and clinical researchers with tools for assay development, evaluation and implementation. From small specimen aliquots to bulk-processed material and custom prospective collection services, we offer difficult-to-find, reliable materials for development, manufacturing, and validation of IVD products.

### THE BENEFITS OF SERACARE'S DISEASE STATE MATERIALS

- Streamline procurement for a wide range of disease state analytes
- Challenge your assay with characterized positive specimens with well-documented donor demographics
- Catered to your specialized requirements with custom processing options and prospective collection services

### COMPLIANCE IS IN OUR NATURE

Our Disease State Materials team includes members with more than 20 years experience working with global IVD companies, so we understand your submission requirements. We handle every aspect of collections compliance — from drafting and submitting protocols to negotiating with IRBs, if required — saving you time and reducing your regulatory risk.

### COMPREHENSIVE, CUSTOMIZED SOLUTIONS

In addition to inventoried disease state specimens, SeraCare can manage every aspect of your own custom collections program, tailored to your acquisition strategy. We have a 25-year track record of successful collections for a wide range of disease states, around the world. This, together with our materials processing expertise, enables us to deliver materials to meet your specific requirements, when you need them.

### SPECIMENS

Specimen samples are collected from individual donors worldwide. Sample types include raw plasma, serum and other biological matrices. They are extensively characterized on industry-leading IVD platforms and assays to provide detailed reactivity profiles. Positive, negative, and rare specimens are available in a variety of pre-packaged sizes to expedite order processing and shipping.

### ACCUTYPE™ VIRAL ISOLATES

SeraCare's high-titer cultured viral isolates and purified RNA are particularly helpful for HIV assays, where diverse geographical genotypes are difficult to find. We have collections from USA to Zaire and everywhere in between. SeraCare's AccuType™ collection has genotypes spanning both group M and group O; a unique portfolio of rare HIV isolates unlikely to be found anywhere else.



## OUR DISEASE STATE MATERIALS PROVIDE BIOLOGICAL MATERIALS FOR:

### INFECTIOUS DISEASE ANALYTES

SeraCare offers a wide range of analytes for a large number of infectious diseases from Chagas, Dengue and West Nile Virus, to HIV, Hepatitis and Syphilis to name just a few. Our inventory continues to expand to meet the needs of our customers.

### WOMEN'S HEALTH

SeraCare is committed to supporting efforts to develop innovative assays and therapies for women's health, targeting diseases such as CT/NG, HPV, HSV, and more. We can provide a variety of sample types, including urine, Pap specimens, swab specimens, and matched sets tailored to your specific project.

### AUTOIMMUNE DISEASE

Seracare offers characterized analytes from a wide range of autoimmune disease conditions — including Rheumatoid Arthritis, Systemic Lupus, Thyroid disorders, and Celiac disease.

### NORMAL MATERIALS

Negative disease state specimens are equally as important as positives to ensure platform/assay accuracy and reproducibility. We can also provide a variety of specimen types, such as normal human samples, synthetic cerebrospinal fluid, cord blood, whole blood, normal human plasma (EDTA, 4% sodium citrate) and serum, pooled sputum, urine and more.

## AccuSet™ Performance Panels

### HIV

MATERIAL #	PANEL	# MEMBERS	FILL SIZE (ML)
0800-0262	HIV-1 Group O Performance Panel	5	1.2
0800-0315	HIV-1 RNA EDTA Performance Panel	12	1.2
0800-0492	HIV Worldwide Performance Panel	15	1.0
0800-0420	HIV-1 p24 Ag Mixed Titer Performance Panel	15	1.0
0800-0436	HIV-1 Mixed Titer Performance Panel	20	1.0
0800-0508	HIV-1/2 Performance Panel	13	1.0
0800-0457	HIV-1 Low Titer Performance Panel	20	1.0
0800-0394	HIV-1 Early Infection Performance Panel	25	1.0





## HEPATITIS (HAV, HBV, HCV)

MATERIAL #	PANEL	# MEMBERS	FILL SIZE (ML)
0805-0216	Anti-HBc IgM Mixed Titer Performance Panel Modified	22	1.0
0805-0391	HBsAg Performance Panel	25	1.5
0805-0341	Anti-HBc/HBs Performance Panel	20	1.5
0810-0277	HCV Performance Panel	25	1.0
0810-0230	HCV Worldwide Performance Panel	22	1.0
0820-0443	HAV Mixed Titer Performance Panel	21	1.0
0810-0256	HCV Low Titer Performance Panel	20	1.0
0805-0370	HBsAg Low Titer Performance Panel	20	1.5

## TORCH

MATERIAL #	PANEL	# MEMBERS	FILL SIZE (ML)
0815-0003	HSV-1/2 Mixed Titer Performance Panel	21	1.2
0820-0321	Toxoplasmosis Performance Panel	24	1.0
0820-0347	Rubella Performance Panel	20	1.0
0820-0389	CMV Performance Panel	20	1.0

## VECTOR-BORNE DISEASES

MATERIAL #	PANEL	# MEMBERS	FILL SIZE (ML)
0845-0142	Zika IgM Performance Panel	10	1.0
0845-0153	Dengue Performance Panel	15	1.0
0845-0169	Lyme Performance Panel	15	1.0
0845-0185	Babesia Performance Panel	15	1.0
0845-0222	Chagas (T. cruzi) Performance Panel	20	1.0

## OTHER DISEASES

MATERIAL #	PANEL	# MEMBERS	FILL SIZE (ML)
0820-0481	HTLV-I/II Mixed Titer Performance Panel	21	1.2
0820-0300	Syphilis Performance Panel	20	1.0
0840-0001	Autoimmune Performance Panel	20	1.0
0850-0024	Anti-EBV Mixed Titer Performance Panel	21	1.2
0820-0410	SARS-CoV-2 Performance Panel	11	1.0



## AccuVert™ Seroconversion Panels

### HIV

MATERIAL #	PANEL	# MEMBERS	FILL SIZE (ML)	HIV-1 RNA	HIV-1 P24 AG	HIV-1 AB
0600-0227	HIV-1 Seroconversion Panel AV	4	1.0	▲	▲	○
0600-0230	HIV-1 Seroconversion Panel AY Modified	4	1.0	▲	▲	▲
0600-0232	HIV-1 Seroconversion Panel AZ	4	1.0	▲	▲	▲
0600-0237	HIV-1 Seroconversion Panel BC	4	1.0	●	▲	▲
0600-0240	HIV-1 Seroconversion Panel BF	5	1.0	▲	▲	▲
0600-0243	HIV-1 Seroconversion Panel	9	1.0	▲	▲	○
0600-0244	HIV-1 Seroconversion Panel	6	1.0	▲	▲	○
0600-0245	HIV-1 Seroconversion Panel	7	1.0	▲	▲	◻
0600-0246	HIV-1 Seroconversion Panel	6	1.0	▲	▲	○
0600-0248	HIV-1 Seroconversion Panel	10	1.0	▲	▲	▲
0600-0249	HIV-1 Seroconversion Panel	6	1.0	▲	▲	▲
0600-0251	HIV-1 Seroconversion Panel	10	1.0	▲	▲	▲
0600-0252	HIV-1 Seroconversion Panel	4	1.0	●	●	▲
0600-0253	HIV-1 Seroconversion Panel	4	1.0	●	▲	▲
0600-0256	HIV-1 Seroconversion Panel	4	1.2	●	▲	▲
0600-0258	HIV-1 Seroconversion Panel	4	1.2	▲	▲	◻
0600-0260	HIV-1 Seroconversion Panel	5	1.2	▲	▲	○
0600-0261	HIV-1 Seroconversion Panel	4	1.2	●	▲	○
0600-0262	HIV-1 Seroconversion Panel	4	1.2	●	▲	▲
0600-0263	HIV-1 Seroconversion Panel	7	1.2	▲	▲	○
0600-0265	HIV-1 Seroconversion Panel	9	1.0	▲	▲	○
0600-0270	HIV-1 Seroconversion Panel	4	1.0	▲	○	▲
0600-0271	HIV-1 Seroconversion Panel	8	1.0	●	◆	◆
0600-0272	HIV-1 Seroconversion Panel	6	1.0	▲	◆	▲

**LEGEND**

- ▲ converts negative to positive
- ▼ converts positive to negative
- ◆ variable conversion
- all members negative
- all members positive
- ◻ members negative or indeterminate
- NT not tested



## HBV

MATERIAL #	PANEL	# MEMBERS	FILL SIZE (ML)	HBV DNA	HBSAG	HBEAG	HBC IGM AB	HBC TOTAL AB	HBE AB	HBS AB
0605-0028	HBV Seroconversion Panel	8	1.5	●	▲	NT	NT	NT	NT	NT
0605-0038	HBV Seroconversion Panel	8	1.5	●	●	▲	○	○	NT	NT
0605-0039	HBV Seroconversion Panel	5	1.5	●	▲	○	○	○	○	○
0605-0041	HBV Seroconversion Panel	5	1.5	●	▲	▲	○	○	○	○
0605-0059	HBV Seroconversion Panel	8	1.5	●	▲	○	○	○	○	○
0605-0062	HBV Seroconversion Panel	6	1.5	●	▲	▲	▲	▲	○	○

## HCV

MATERIAL #	PANEL	# MEMBERS	FILL SIZE (ML)	HCV RNA	HCV AB (EIA)	HCV AB RIBA
0610-0217	HCV Seroconversion Panel	7	1.0	▲	▲	▲
0610-0221	HCV Seroconversion Panel	6	1.2	●	▲	▣
0610-0223	HCV Seroconversion Panel	6	1.2	●	▲	▲
0610-0224	HCV Seroconversion Panel	5	1.2	●	▲	▲
0610-0225	HCV Seroconversion Panel	5	1.2	●	▲	▣
0610-0293	HCV Seroconversion Panel	5	1.2	▲	○	○
0610-0294	HCV Seroconversion Panel	9	1.2	▲	○	○
0610-0295	HCV Seroconversion Panel	6	1.2	▲	○	○

## OTHER DISEASES

MATERIAL #	PANEL	# MEMBERS	FILL SIZE (ML)
0615-0017	Syphilis Seroconversion Panel	9	1.2
0615-0026	HAV Seroconversion Panel	8	1.2
0615-0038	Chagas (T. cruzi) Seroconversion Panel	10	1.2
0615-0039	CMV Seroconversion Panel	4	1.2
0820-0187	West Nile Virus (WNV) Seroconversion Panel	5	1.5
0820-0465	SARS-CoV-2 Seroconversion Panel	14	1.0

### LEGEND

- ▲ converts negative to positive
- all members positive
- ▽ converts positive to negative
- ▣ members negative or indeterminate
- ◆ variable conversion
- NT not tested
- all members negative



## AccuSpan™ Linearity Panels

MATERIAL #	PANEL	# MEMBERS	FILL SIZE (ML)
2410-0161	HBsAg Sensitivity Panel	15	1.5
2410-0162	HBV DNA Linearity Panel	9	1.2
2410-0166	HCV RNA Linearity Panel (Plasma)	8	1.2
2410-0174	CMV DNA Linearity Panel	9	2.0
2410-0221	HIV-1 RNA Linearity Panel	10	1.2
2410-0318	Zika RNA Linearity Panel	7	1.5
2410-0327	HCV RNA Linearity Panel (AccuPlex™)	8	1.2

## AccuTrak™ Qualification Panels

MATERIAL #	PANEL	# MEMBERS	FILL SIZE (ML)
2400-0140	HIV-1 RNA/HCV RNA/HBV DNA Qualification Panel	5	4.0
2400-0141	HBsAg Qualification Panel	6	2.0
2400-0145	Anti-HBc Qualification Panel	6	2.0
2400-0148	Anti-HCV Qualification Panel	6	1.0
2400-0158	HIV-1/2/O/p24 Qualification Panel	6	3.5
2400-0160	Anti-HIV-1/2 Qualification Panel	6	1.0
2400-0161	HPV Genotype Qualification Panel	25	4.0
2400-0163	Syphilis Qualification Panel	6	2.0
2400-0164	Anti-CMV Qualification Panel	6	3.0
2400-0181	Anti-HTLV-I/II Qualification Panel	6	1.5
2400-0182	HCV RNA Genotype Qualification Panel	9	1.2
2400-0201	CMV DNA Qualification Panel	9	2.0
2400-0220	Dengue Synthetic RNA Qualification Panel	4	1.0





## Disease State Material

### NORMAL/HEALTHY OR SYNTHETIC MATRICES

MATERIAL #	PRODUCT NAME
0175-0007	Synthetic Cerebral Spinal Fluid
0300-0005	Normal Human Serum
0300-0008	Normal Human K2 EDTA Plasma
0375-0002	Normal Human Pooled Sputum
0375-0003	Cord Serum
0300-0002	Normal Human Plasma

### HIV

MATERIAL #	PRODUCT NAME
0315-0020	HIV-1/2 Antibody Positive Plasma
0315-0024	HIV-1 Antibody Confirmed Positive Plasma
0315-0028	HIV-2 Antibody Confirmed Positive Plasma
0315-0031	HIV-2 Antibody Confirmed Positive, HIV-1 Antibody Negative Plasma
0315-0034	HIV-1 Antigen Positive Plasma
0315-0037	HIV-1 RNA Positive Plasma
0315-0040	HIV-1 RNA Positive, HIV-1/2 Antibody Positive Plasma
0315-0043	HIV-1 RNA Positive, HIV-1/2 Antibody Negative Plasma
0315-0046	HIV-1 Subtype A Positive Plasma
0315-0049	HIV-1 Subtype B Positive Plasma
0315-0052	HIV-1 Subtype C Positive Plasma
0315-0055	HIV-1 Subtype D Positive Plasma
0315-0058	HIV-1 Subtype F Positive Plasma
0315-0061	HIV-1 Subtype K Positive Plasma
0315-0064	HIV-1 Subtype CRF01_AE Positive Plasma
0315-0067	HIV-1 Subtype CRF02_AG Positive Plasma
0315-0070	HIV-1 Subtype CRF03_AB Positive Plasma
0315-0073	HIV-1 Other Subtype Positive Plasma
0315-0076	HIV-1 Group O Positive Plasma
0315-0079	HIV-1 RNA EDTA Positive Plasma



## HEPATITIS

MATERIAL #	PRODUCT NAME
0301-0006	HAV IgM Antibody Positive Plasma >4 S/CO
0301-0010	HAV IgG/Total Antibody Positive Plasma >2 S/CO
0301-0014	HAV RNA Positive Plasma
0305-0018	HBc IgM Antibody Positive Plasma >4 S/CO
0305-0022	HBc IgM Antibody Positive Plasma >2 S/CO
0305-0026	HBc Total Antibody Positive, HBsAg Positive Plasma
0305-0030	HBc Total Antibody Positive, HBsAg Negative Plasma
0305-0034	HBe Antibody Positive Plasma
0305-0038	HBs Antibody Positive Plasma >2 S/CO
0305-0042	HBs Antibody Positive Plasma >20 mIU/mL
0305-0046	HBs Antibody Positive Plasma >200 mIU/mL
0305-0050	HBs Antibody Positive Plasma >1000 mIU/mL
0305-0054	HBeAg Positive Plasma >2 S/CO
0305-0058	HBsAg Positive Plasma
0305-0066	HBsAg Subtype AY Positive Plasma
0305-0070	HBsAg Subtype AD Positive Plasma
0305-0074	HBV DNA Positive Plasma
0305-0078	HBV Genotype A Positive Plasma
0305-0081	HBV Genotype B Positive Plasma
0305-0084	HBV Genotype C Positive Plasma
0305-0087	HBV Genotype D Positive Plasma
0305-0090	HBV Genotype E Positive Plasma
0305-0093	HBV Genotype F Positive Plasma
0305-0099	HBV Genotype H Positive Plasma
0310-0020	HCV Antibody Positive Plasma
0310-0024	HCV Antibody Confirmed Positive Plasma
0310-0028	HCV Antigen Positive Plasma
0310-0031	HCV RNA Positive Plasma
0310-0034	HCV RNA Positive, HCV Antibody Positive Plasma
0310-0037	HCV RNA Positive, HCV Antibody Negative Plasma
0310-0040	HCV RNA Genotype 1 Positive Plasma
0310-0043	HCV RNA Genotype 1a Positive Plasma
0310-0046	HCV RNA Genotype 1b Positive Plasma
0310-0049	HCV RNA Genotype 2 Positive Plasma



0310-0052	HCV RNA Genotype 2a Positive Plasma
0310-0055	HCV RNA Genotype 2b Positive Plasma
0310-0058	HCV RNA Genotype 3 Positive Plasma
0310-0061	HCV RNA Genotype 4 Positive Plasma
0310-0064	HCV RNA Genotype 5 Positive Plasma
0310-0067	HCV RNA Genotype 6 Positive Plasma
0310-0070	HCV RNA EDTA Positive Plasma
0311-0010	HEV IgG Antibody Positive Plasma >2 S/CO
0311-0014	HEV IgG Antibody Positive Plasma >4 S/CO
0311-0018	HEV RNA Positive Plasma
0301-0002	HAV IgM Antibody Positive Plasma >2 S/CO
0305-0061	HBsAg Quantitative Positive Plasma
0311-0005	HEV IgM Antibody Positive Plasma >4 S/CO

## TORCH (TOXOPLASMA, RUBELLA, CYTOMEGALOVIRUS, AND HERPES)

MATERIAL #	PRODUCT NAME
0320-0004	Toxoplasma IgG Antibody Positive Plasma
0320-0008	Toxoplasma IgM Antibody Positive Plasma
0320-0012	ToRCH Negative Plasma
0320-0016	Cytomeglovirus IgG Antibody Plasma
0320-0020	Cytomeglovirus IgM Antibody Plasma
0320-0024	Rubella IgG Antibody Positive Plasma
0320-0028	Rubella IgM Antibody Positive Plasma
0320-0032	HSV-1 IgG Antibody Positive Plasma
0320-0036	HSV-1 IgM Antibody Positive Plasma
0320-0040	HSV-2 IgG Antibody Positive Plasma
0320-0044	HSV-2 IgM Antibody Positive Plasma

## VECTOR-BORNE

MATERIAL #	PRODUCT NAME
0325-0014	Dengue IgG Antibody Positive Plasma
0325-0018	Dengue IgM Antibody Positive Plasma
0325-0041	Chagas Antibody Positive Plasma
0325-0045	Lyme Disease IgG Antibody Positive Plasma
0325-0049	Lyme Disease IgM Antibody Positive Plasma
0325-0053	Lyme Disease Total Antibody Positive Plasma



0325-0058	West Nile Virus IgM Antibody Positive Plasma
0325-0062	West Nile Virus IgG Antibody Positive Plasma
0325-0073	Zika IgG Antibody Positive Plasma
0325-0079	Zika IgM Antibody Positive Plasma
0325-0083	Malaria Positive Plasma
0325-0026	Dengue RNA Positive Plasma
0325-0091	Babesia Antibody Positive Plasma

## AUTOIMMUNE

MATERIAL #	PRODUCT NAME
0340-0002	Anti-Mitochondrial Antibody (AMA) Positive Plasma
0340-0006	Antinuclear Antibody (ANA) Centromere Positive Plasma
0340-0010	Antinuclear Antibody (ANA) Homogeneous Positive Plasma
0340-0014	Antinuclear Antibody (ANA) Nucleolar Positive Plasma
0340-0018	Antinuclear Antibody (ANA) Speckled Positive Plasma
0340-0022	Antinuclear Antibody (ANA) Other Pattern Positive Plasma
0340-0030	Double Stranded DNA (dsDNA) Antibody Positive Plasma
0340-0034	Gliadin IgA Antibody Positive Plasma
0340-0038	Gliadin IgG Antibody Positive Plasma
0340-0042	Jo-1 Antibody Positive Plasma
0340-0046	Rheumatoid Factor (RF) Antibody Positive Plasma <1000 IU/mL
0340-0050	Rheumatoid Factor (RF) Antibody Positive Plasma >5000 IU/mL
0340-0054	Rheumatoid Factor (RF) Antibody Positive Plasma 1001-2000 IU/mL
0340-0058	Rheumatoid Factor (RF) Antibody Positive Plasma 2001-4000 IU/mL
0340-0062	Rheumatoid Factor (RF) Antibody Positive Plasma 4001-5000 IU/mL
0340-0066	Ribonucleoprotein (RNP) Antibody Positive Plasma
0340-0070	Smith/Ribonucleoprotein (SM/RNP) Antibody Positive Plasma
0340-0074	SCL-70 Antibody Positive Plasma
0340-0078	Smith Antibody Positive Plasma
0340-0082	SSA Antibody Positive Plasma
0340-0086	SSB Antibody Positive Plasma
0340-0090	Thyroglobulin (TG) Antibody Positive Plasma
0340-0094	Thyroid Peroxidase Antibody (TPO) Positive Plasma
0340-0098	Ribosomal P Antibody Positive Plasma
0340-0026	Cardiolipin IgG Antibody Positive Plasma





## OTHER INFECTIOUS

MATERIAL #	PRODUCT NAME
0325-0029	HTLV-I Confirmed Antibody Positive Plasma
0325-0033	HTLV-II Confirmed Antibody Positive Plasma
0325-0037	HTLV-I/II Antibody Positive Plasma
0345-0004	Epstein-Barr Virus (EBV) VCA IgM Positive Plasma
0345-0008	Epstein-Barr Virus (EBV) VCA IgG Positive Plasma
0345-0012	Epstein-Barr Virus (EBV) Negative Plasma
0345-0016	Epstein-Barr Virus (EBV) EBNA IgM Antibody Positive Plasma
0345-0020	Epstein-Barr Virus (EBV) EBNA IgG Antibody Positive Plasma
0350-0003	Varicella Zoster Virus (VZV) IgM Antibody Positive Plasma
0350-0007	Varicella Zoster Virus (VZV) IgG Antibody Positive Plasma
0350-0011	Parvovirus IgM Antibody Positive Plasma
0350-0015	Parvovirus IgG Antibody Positive Plasma
0350-0019	Parvovirus DNA Positive Plasma
0350-0023	Mycoplasma IgM Antibody Positive Plasma
0350-0027	Mycoplasma IgG Antibody Positive Plasma
0350-0031	Chlamydia IgM Antibody Positive Plasma
0350-0035	Chlamydia IgG Antibody Positive Plasma
0350-0039	Chlamydia IgA Antibody Positive Plasma
0365-0003	Syphilis (T. pallidum) IgG Antibody Positive Plasma
0365-0007	Rapid Plasma Reagin (RPR) Positive Plasma
0365-0010	Syphilis (T. pallidum) IgM Antibody Positive Plasma
0325-0087	SARS-CoV-2 Antibody Positive Plasma

## AccuType™ Viral Isolates and Purified RNA

### HIV VIRAL ISOLATES

MATERIAL #	PRODUCT NAME	COUNTRY OF ORIGIN	ISOLATE ID
0400-0001	HIV-1 Genotype CRF02-AG	Djibouti	DJ258
0400-0002	HIV-1 Genotype A	Uganda	UG273
0400-0003	HIV-1 Genotype CRF02-AG	Djibouti	DJ263
0400-0004	HIV-1 Genotype A	Uganda	UG275
0400-0005	HIV-1 Genotype CRF02-AG	Liberia	POC44951
0400-0006	HIV-1 Genotype AG	Ghana	I-2496
0400-0007	HIV-1 Genotype B	Thailand	BK132



0400-0008	HIV-1 Genotype B	USA	US2
0400-0009	HIV-1 Genotype B	Brazil	BZ167
0400-0010	HIV-1 Genotype B	USA	US4
0400-0011	HIV-1 Genotype B	USA	93US144
0400-0012	HIV-1 Genotype B	Thailand	CM237
0400-0013	HIV-1 Genotype B	USA	US1
0400-0014	HIV-1 Genotype B	USA	93US143
0400-0015	HIV-1 Genotype B	USA	93US141
0400-0016	HIV-1 Genotype B	USA	US3
0400-0017	HIV-1 Genotype C	Ethiopia	ETH2220
0400-0018	HIV-1 Genotype C	Senegal	SE364
0400-0019	HIV-1 Genotype C	Somalia	SM145
0400-0020	HIV-1 Genotype C	Djibouti	DJ259
0400-0021	HIV-1 Genotype C	Uganda	UG268
0400-0022	HIV-1 Genotype C	Zambia	ZAM18
0400-0023	HIV-1 Genotype C	Unknown	I-2516
0400-0024	HIV-1 Genotype D	Senegal	SE365
0400-0025	HIV-1 Genotype D	Uganda	UG274
0400-0026	HIV-1 Genotype D	Uganda	UG270
0400-0027	HIV-1 Genotype CRF01-AE	Thailand	CM240
0400-0028	HIV-1 Genotype CRF01-AE	Indonesia	ID12
0400-0029	HIV-1 Genotype CRF01-AE	Thailand	CM235
0400-0030	HIV-1 Genotype CRF01-AE	Indonesia	ID17
0400-0031	HIV-1 Genotype CRF01-AE	Thailand	NP1465
0400-0032	HIV-1 Genotype CRF01-AE	Thailand	CM243D
0400-0033	HIV-1 Genotype CRF01-AE	Thailand	42368
0400-0034	HIV-1 Genotype CRF01-AE	Thailand	POC30506
0400-0035	HIV-1 Genotype CRF01-AE	Thailand	NP03
0400-0036	HIV-1 Genotype CRF01-AE	Thailand	CM238
0400-0037	HIV-1 Genotype F	Brazil	BZ163
0400-0038	HIV-1 Genotype F	Brazil	BZ126
0400-0039	HIV-1 Genotype F	Brazil	BZ162
0400-0040	HIV-1 Genotype F	Romania	BCI-R07
0400-0041	HIV-1 Genotype F	Romania	BCI-R08
0400-0042	HIV-1 Genotype CRF06	Zaire	BCF-DIOUM
0400-0043	HIV-1 Genotype G	Kenya	HH8793
0400-0044	HIV-1 Genotype G	Zaire	BCF-KITA



0400-0045	HIV-1 Group O	Cameroon	BCF06
0400-0046	HIV-1 Group O	Cameroon	BCF11
0400-0047	HIV-1 Group O	USA	I-2478B
0400-0048	HIV-1 Group O	Spain	I-2481
0400-0051	HIV-1 Genotype A	Kyrgyzstan	9250622-01
0400-0094	HIV-2 Subtype A	Africa	NIH-Z
0400-0095	HIV-2 Subtype B	USA	Seattle

## HIV-1 PURIFIED RNAS

MATERIAL #	PRODUCT NAME	COUNTRY OF ORIGIN	ISOLATE ID
0400-0075	HIV-1 Purified RNA Genotype AG	Ghana	I-2496
0400-0076	HIV-1 Purified RNA Genotype CRF02-AG	Liberia	POC44951
0400-0077	HIV-1 Purified RNA Genotype B	Thailand	BK132
0400-0078	HIV-1 Purified RNA Genotype B	USA	US1
0400-0079	HIV-1 Purified RNA Genotype C	Djibouti	DJ259
0400-0080	HIV-1 Purified RNA Genotype C	Unknown	I-2516
0400-0081	HIV-1 Purified RNA Genotype D	Uganda	UG274
0400-0082	HIV-1 Purified RNA Genotype D	Senegal	SE365
0400-0083	HIV-1 Purified RNA Genotype CRF01-AE	Thailand	42368
0400-0084	HIV-1 Purified RNA Genotype CRF01-AE	Thailand	POC30506
0400-0085	HIV-1 Purified RNA Genotype F	Brazil	BZ126
0400-0086	HIV-1 Purified RNA Genotype F	Brazil	BZ162
0400-0087	HIV-1 Purified RNA Genotype CRF06	Zaire	BCF-DIOUM
0400-0088	HIV-1 Purified RNA Genotype G	Kenya	HH8793
0400-0089	HIV-1 Purified RNA Genotype G	Zaire	BCF-KITA
0400-0090	HIV-1 Purified RNA Genotype O	Cameroon	BCF06
0400-0091	HIV-1 Purified RNA Genotype O	Cameroon	BCF11
0400-0092	HIV-1 Purified RNA Genotype O	USA	I-2478B
0400-0093	HIV-1 Purified RNA Genotype O	Spain	I-2481

## OTHER VIRUSES

MATERIAL #	PRODUCT NAME	ISOLATE ID
0410-0002	WNV Lineage I	2001-6263
0410-0003	WNV Lineage II	956-99
0410-0004	EBV	B95-8
0410-0014	HSV-1	VR539
0410-0015	HSV-2	VR540



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